



United States
Department of
Agriculture

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Animal and
Plant Health
Inspection
Service

Marketing & Regulatory
Programs Business
Services

Animal Protection and
Quarantine

Center for Plant Health
Science and Technology

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Suite 400
Raleigh, NC 27606

Dear Sir or Madam,

Thank you for your interest in participating in the provisional approval process for the production of diagnostic determinations in the USDA APHIS PPQ *Phytophthora ramorum* national survey program. This process is a pilot program designed to meet the emergency needs of APHIS to provide timely and accurate determinations for the majority of samples collected in the national survey. This process will also serve as a template for future interactions of APHIS with laboratories outside the USDA system. Also, experience gained from this process will be used to help APHIS develop a more general accreditation framework for diagnostic protocols.

The first component identified as necessary to facilitate provisional approval includes reading and understanding the APHIS provisional lab approval document as well as the APHIS approved diagnostic protocols. The APHIS provisional lab approval document should be included with this letter and the current APHIS approved diagnostic protocols are available on the internet at:

<http://www.aphis.usda.gov/ppq/ispm/pramorum/>. Reading and understanding of these documents is an important first step because diagnostic labs wishing to fully participate in the program must be capable of performing all the molecular diagnostics outlined in the protocols. The physical layout of the facility, the equipment, and the training of personnel all must be suitable and maintained for the provisional approval to remain effective. Labs wishing to supplement their *Phytophthora ramorum* diagnostics with attempts to culture the pathogen require additional facilities and precautions to prevent cross-contamination of the samples by DNA of the organism.

Additional component that are necessary to participate in the provisional approval process includes: a schematic description of the lab and list of security measures, a list of relevant capital equipment, and the eventual development of SOP's for lab handling of samples. In addition, a suitable biographical statement is needed for the principal diagnostician as well as any personnel leading or making decisions on key diagnostic processes. A Curriculum Vitae or a descriptive narrative are both suitable, as long as they contain: explicit statements on education and degrees earned, professional development, and experience in molecular diagnostic techniques.

The remaining key components in the process extend from the primary components. These include: an inspection of the diagnostic facilities, a training visit of the principal diagnostician to the National Plant Germplasm and Biotechnology Laboratory (NPGBL) in Beltsville, MD, and a pre-screen of a proficiency panel of diagnostic DNA samples. Once these components have been completed, a diagnostic lab will be provisionally approved by APHIS to make diagnostic determinations of



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samples for the *P. ramorum* diagnostic program. DNA of samples determined to be positive for *P. ramorum* still need to be forwarded to the NPGBL for positive confirmation, but these samples remain a small proportion of the total samples diagnostic labs have processed so far.

The provisional approval process is still evolving as more diagnostic labs enter the process, so components such as expiration of approval, subsequent lab inspections and proficiency panels, and specific contractual details are still being developed. Our goal is to streamline the current process so that it harmonizes with standard accreditation protocols (such as ISO 17025) and can be applied to molecular diagnostics for other pathogens. We will do our best to inform and solicit comment from the current participating diagnostic labs of progress in the development of these programs.